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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,390	09/08/2000	Arthur J. Coury	00986-086001/5182	3456

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,390	COURY ET AL	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted March 9, 2005 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zajaczkowski (US 5,726,250) in view of Hubbell (US 5,410,016, IDS).

Zajaczhowski teaches a crosslinked water-absorbent copolymers useful for wound dressing or medical adhesive. The copolymer is made of macromers and monomers, wherein the macromer has a hydrophilic region, which may be polyethylene glycol, and acrylate terminal group, with molecular weight about 300-50,000, and preferably 300 to 3000; the monomers may be hydrophilic, such as hydroxyethyl acrylate, vinyl pyrrolidone, diacetone acrylamide, or hydrophobic, such as butyl acrylate. The amount of macromer may up to 35 % by weight. The crosslinking may be realized by employing polyfunctional macromers or monomers. See, particularly, the abstract, columns 4-5, column 6, lines 52-62, the example in columns 9-12 and the claims. When used as wound dressing composition, the copolymer may be incorporated with therapeutical agents as served as sustained release device. See, particularly, column 8, line 48-63. As to the employment of the particularly moiety defined in claims 47, note, acrylate and lactate are known to be useful in the macromer, therefore, employ the ester of the two compounds

herein is obvious. Polymerization initiator is required in Zajaczkowski's composition. See, particularly, the examples.

Zajaczhowski does not teach expressly to employ a macromers having at least two polymerizable groups, or the particular, macromers.

However, Hubbell et al. teach a biocompatible, biodegradable, polymerizable and at least substantially water soluble macromers having a variety of uses in vivo. The macromer has molecular weight about 400 to 30,000, and has polyethylene glycol moiety and alpha hydroxyl acid moiety, such as lactic acid. The macromer has at least two polymerizable terminal acrylate moieties. The hydrogel obtained from the macromer is particularly useful for wound dressing, tissue adhesives, tissue support, and control release of therapeutical agents. The macromer may be polymerized by a photoinitiator. See column 9.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the macromers as disclosed by Hubbell et al. to make the crosslinked water-absorbent copolymers.

A person of ordinary skill in the art would have been motivated to employ the macromers as disclosed by Hubbell et al. to make the crosslinked water-absorbent copolymers because of the advantage disclosed by Hubble, e.g., biocompatible, biodegradable, polymerizable, and further the macromer has more than one polymerizable groups, meet the requirement for internal crosslinking as defined by Zajaczhowski, and provide a means of crosslinking. Further, the macromer has similar molecular weight and components to those employed by Zajaczhowski, and is particularly known to be useful in forming materials suitable for tissue adhesive wound dressing and controlled release.

3. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zajaczkowski (US 5,726,250) in view Jarrett et al. (WO 98/12243, IDS).

Zajaczhowski teaches a crosslinked water-absorbent copolymers useful for wound dressing and medical adhesive. The copolymer is made of macromers and monomers, wherein the macromer has a hydrophilic region, which may be polyethylene glycol, and acrylate terminal, with molecular weight about 300-50,000, and preferably 300 to 3000; the monomers may be hydrophilic, such as hydroxyethyl acrylate, vinyl pyrrolidone, diacetone acrylamide, or hydrophobic, such as butyl acrylate. The amount of macromer may up to 35 % by weight. The crosslinking may be realized by employing polyfunctional macromers or monomers. See, particularly, the abstract, columns 4-5, column 6, lines 52-62, the example in columns 9-12 and the claims. When used as wound dressing composition, the copolymer may be incorporated with therapeutical agents as served as sustained release device. See, particularly, column 8, line 48-63. Polymerization initiator is required in Zajaczkowski's composition. See, particularly, the examples.

Zajaczhowski does not teach expressly to employ a macromers having at least two polymerizable groups, or the particular, macromers.

However, Jarrett et al. teaches a macromer containing polyethylene glycol moiety and carbonate moiety (e.g., trimethylene carbonate), and/or lactate moiety, and with more than one terminal acrylate groups. The macromer is particularly useful for adhere or seal tissues together (wound dressing), or for controlled delivery of therapeutical agent. See, particularly, the abstract, pages 23-24, and the claims. The macromer is advantageous because it can be used to coat and or bond together any of a wide variety of surfaces, including bone or cartilage. See pages 30-31.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the macromers as disclosed by Jarrett et al. to make the crosslinked water-absorbent copolymers.

A person of ordinary skill in the art would have been motivated to employ the macromers as disclosed by Jarrett et al. to make the crosslinked water-absorbent copolymers because of the known advantage of the macromer, such as it can be used to coat and or bond together any of a wide variety of surfaces, including bone or cartilage. Further, the macromer has more than one polymerizable groups, meet the requirement for internal crosslinking as defined by Zajaczhowski, providing a means for crosslinking. Further, the macromer has similar molecular weight and components to those employed by Zajaczhowski, and is particularly known to be useful in forming materials suitable for wound dressing and controlled release. As to the employment of the particularly moiety defined in claims 47, note, acrylate and lactate are known to be useful in the macromer, therefore, employ the ester of the two compounds herein is obvious. As to the particular physical properties herein recited, note a composition, as suggested herein, comprising the macromer, e.g., 35KT (example in Jarret) and the monomer disclosed by Zajaczhowski would reasonably meet the limitation since the composition meet all the material limitations herein recited. Note a physical property of a composition cannot be separated from the composition. Further, one of ordinary skill in the art would have reasonable expected the composition as suggested herein would be useful for bonding or repairing bone or cartilage since the macromer is particularly known for such purpose.

Response to the Arguments

Applicants' remarks submitted March 9, 2005 have been fully considered, but are not persuasive.

Applicants' characterization of Zajaczhowski's teaching is incomplete. What applicant described, i.e., forming a graft polymer, followed by crosslinking, is just one embodiment of Zajaczhowski's teaching, i.e. external crosslinking. Zajaczhowski particularly states "The crosslinking reaction which is contemplated is covalent by nature and may be achieved by incorporating into the polymerization mixture (for internal crosslinking) a polyfunctional ethylenically unsaturated compound in an amount sufficient to provide the desired crosslinking." Col. 6, lines 54-60. diester of methacrylic acid is particularly mentioned. See, col. 6, lines 63-67. It is apparent that when internal crosslinking is used, it is one step reaction, i.e. mixing all the monomer and macromer with the crosslinking agent before the polymerization. It is noted that Zajaczhowski does not disclose particular examples for internal crosslinking. However, under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. Take the cited references as a whole, it would have been obvious to incorporate a difuctional macromer, such as a macromer of diacrylate (diester of acrylic acid) in the polymerization mixture. It is noted that the claims herein do not have limitation of the least amount difunctional macromer. Therefore, the 0.02 to about 2 percentage of difunctional macromer would meet the requirements herein.

Following subject matter are allowable over the prior art:

A composition for forming a water-absorbing, high modulus polymeric material consisting essentially of at least one macromer and at least one monomer,

wherein the macromer comprises hydrophobic and hydrophilic regions, has a molecular weight of 1000 to 100,000 DA and has at least two polymerizable groups, and the macromer comprises at least 10% (wt/wt) of the composition,

wherein the monomer contains at least one vinyl group and has a molecular weight of less than 1,000 Da, and

wherein the monomer comprises at least 30% (wt/wt) of the composition, and

wherein the composition forms a gel upon polymerization, and the gel is characterized as having the following properties

a) absorbing water to less than 300% of its initial weight, on equilibration with water or body liquids;

b) having modulus tensile of at least 500kP

c) having a solids content of at least 20% after equilibration in water or body liquids;

d) having an elongation to failure of at least 25% before or after hydration to equilibrium; and

e) being sufficiently biocompatible to permit the treatment or repair of biological tissue, or used as an implant in a patient.

Support of the subject matter is found in the specification and the claims, particularly, pages 6, 20-24.

Applicants' invention distinct from the prior art in that it employs multifunction macromer only in relative large amount (10 % wt), without using monofunctional macromer, and provides superior properties, such as high modulus, high elongation.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617